

## REMARKS

This application is a continuation of serial no. 09/866,443. Claims 1-16 were present in the application when filed and remain pending.

### Rejection under 35 U.S.C. §112, second paragraph

Claims 1-16 are rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the language “at least a portion” is objected to. Claim 1 is amended above to remove the words “at least a portion of” even though Applicants do not necessarily agree with the rejection.

### Rejection under 35 U.S.C. §102

Claims 1 and 7-16 are rejected under 35 U.S.C. §102(b) as being anticipated by Oldroyd et al. (*Aust J. Agric Res*, 1989, 40(3), p. 691-698), or in the alternative by Hansen et al (*Tidsskrift for Planteavl*, 1988, Vol. 92, No. 1 p. 11-15), or Wilson et al. (*Can J. Microbiol.*, June 1970, 16(6) 521-526). The Office Action alleges that these references individually teach inoculation of honeybee colonies with a composition comprising an inoculum of *Bacillus larvae* spores, thereby anticipating a composition as claimed by Applicants. Applicants respectfully submit that, for the reasons discussed below, none of the cited references teach Applicants' claimed composition.

Independent claim 1 of the instant application, as amended above, recites a composition for the treatment or prophylaxis of a bee disease, the composition comprising: a) an inoculum containing one or more microorganisms *that are non-pathogenic to bees* for producing a microflora having therapeutic or prophylactic efficacy against the bee disease; and b) an apicultural delivery vehicle for delivering the inoculum to a component of a bee hive, or to a bee colony that is susceptible to or infected with the bee disease, whereby a remedial and/or protective microflora is established within the hive or the bee colony. Thus, the claimed composition comprising an inoculum of non-pathogenic microorganism is in stark contrast to the

compositions of the cited references which contain an inoculum of the pathogen which applicants' claimed composition seeks to prevent.

Inoculation of bee colonies with the bee pathogen, *Bacillus larvae*, is a conventional methodology used in the apicultural arts to induce foulbrood disease within the colonies for further study and evaluation, hence the title of the Hansen reference, "A preliminary experiment involving induced infection from *Bacillus larvae*." All of the cited references employ the method taught by Hansen in their studies. Furthermore, as taught by the Hansen reference, whether or not a bee colony is affected by the disease depends on factors such as the quantity of *B. larvae* spores introduced or the level of spores present in the particular colony's own honey, environment, hereditary resistance of the bees to foulbrood, etc. The absence of signs of disease in the bee colonies inoculated with *B. larvae* does not indicate that *B. larvae* is non-pathogenic.

Oldroyd, for example, relates to a study of the effect of oxytetracycline hydrochloride treatment on American foulbrood. In these studies, honeybee colonies were treated with oxytetracycline hydrochloride preparations at the time that the colony was inoculated with *Bacillus larvae* spores to induce the disease or after American foulbrood disease signs had developed. Oldroyd (abstract) indicates that *B. larvae* was cultured from adult bee samples from colonies that did not subsequently develop disease signs. Oldroyd does not suggest that these colonies are disease free subsequent to inoculation with *B. larvae*; rather, Oldroyd concludes that these results show that recommended treatments for European foulbrood (EFB) effectively mask American foulbrood (AFB) disease, making it likely that beekeepers treating EFB essentially suppress signs of AFB disease.

It is important to note, therefore, that *B. larvae* is pathogenic to bees. In Oldroyd, the composition with which the bee colony was inoculated comprised a microorganism pathogenic to bees, namely *Bacillus larvae*. Therefore, in as much as Oldroyd et al teaches inoculation of a microorganism that *is* pathogenic to bees, Oldroyd cannot anticipate Applicants' invention.

Similarly, Wilson et al. observed the occurrence of flagellar bundles of the honeybee pathogen subsequent in honeybee larvae subsequent to induction of foulbrood disease by *B. larvae* spore inoculation into a colony. Like Oldroyd, therefore, Wilson does not teach a composition comprising an inoculum of microorganisms that is *non-pathogenic* to bees.

Claims 1 and 7-16 are further rejected under 35 U.S.C. §102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as anticipated by Hoopingarner et al. (*American Bee Journal, 1988, Vol. 128, No. 2, p. 120-121*).

Hoopingarner, like the other cited references, teaches inoculation with *B. larvae* pathogen for the purpose of inducing American foulbrood disease to evaluate the effectiveness of three terramycin formulations on that disease. As with the other cited references, therefore, there is no teaching of a composition comprising an inoculum of non-pathogenic microorganisms for the prevention of *B. larvae* induced foulbrood disease.

Thus, independent claim 1 is not anticipated by the references cited in the Office Action. Furthermore, the dependent claims, because they include all the limitations of the claim from which they ultimately depend, are also deemed patentable in view of the above comments. Withdrawal of the rejection is respectfully requested.

For the foregoing reasons, the claims are believed in condition for allowance and such action is respectfully requested. The dependent claims are believed allowable for the same reasons as the independent claims from which they ultimately depend, as well as for their additional limitations.

Should the Examiner require clarification of any of the above, she is invited to contact Applicants' undersigned attorney at the telephone number listed below.

Respectfully submitted,



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